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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,824

12/30/2004

Martina Boehm

02/104 DBM

5192

7590 02/28/2007
Klaus Schweitzer
ProPat
425 C South Sharon Amity Road
Charlotte, NC 28211

EXAMINER

SHEN, BIN

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/519,824

Applicant(s)

BOEHM, MARTINA

Examiner

Bin Shen

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u> </u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The IDS received 12/30/2004, the preliminary amendment received 12/30/2004 have been entered.

Claims 1-6, 17-25 are presented for examination on the merits.

Claim Objections

1. Claims 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 fails to further limit the subject matter of its dependent claim 2, and it is a repeat of claim 5, which provides the same limitation to claim 2.

Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6, 17 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase "0.5 to 5 U" for the following reasons. It is unclear as to what "U" is actually defining. Further, no definition for "U" is provided

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in the specification to support the claim. Is it defined by concentrations (mg/ml) or activity?

The claims are vague and indefinite because the methods in claims 1 and 2 do not recite clear and positive steps. For example, there is no step a, step b, etc. In claim 1, "which has previously been incubated with urea" is confusing since it is not clear if this happened before this method or is the first step of this method.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 6, 18, 19, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Furlan et al. (Blood 1996;87:4223-4234).

Furlan teaches a method for determining the VWF (von Willebrand factor)-cleaving activity (protease/ADAMTS-13) in blood sample, in which 30 ug/ml of purified, urea treated, protease (ADAMTS-13) free VWF, is added to the test sample/ medium (platelets from plasma) (read on as a kit because the reaction containing an ADAMTS-13-free VWF and platelets, as well as urea), after incubation, the protease activity is determined

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by way of the reduction in the VWF-mediated aggragation of platelets through SDS-agarose gel electrophoresis and immunoblotting method (page 4224, left column, 4th full paragraph to right column 1st-4th full paragraph). The method is carried out in the presence of serine protease inhibitor (page 4225, left column, 2nd full paragraph, line 13: DFP-a strong serine protease inhibitor; page 4225, right column, 2nd full paragraph and Fig. 9).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6, 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furlan et al.

Furlan teaches what is above.

Furlan does not teach the presence of ristocetin in the method, the use of cell extract as test medium, the construction of calibration curve with normal human plasma, and a diagnostic kit contains ristocetin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of

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Furlan et al. by using ristocetin in the method, using cell extract instead of blood sample to test ADAMTS-13 activity, constructing calibration curve and developing a diagnostic kit contains ristocetin because Furlan discusses the important difference of VWF degradation between healthy individuals and thrombotic thrombocytopenic purpura patients (page 4223, left column, lines 10-14, 33-35), thus there is a need to develop a diagnostic kit that is specific for VWF by adding ristocetin (see attached copy from Wikipedia). One would have been motivated to make the modification because Furlan teaches that high molecular weight platelet agglutinating activity determined as ristocetin cofactor (page 4223, right column, lines 9-12) is caused by adding ristocetin only in the presence of VWF (see attached copy of the web page from Wikipedia), and that calibration curve is used to estimated the molecular weight (page 4230, Fig. 10, bottom of the legend), and would reasonably have expected success because use of normal human plasma which has been diluted with varying quantities of inactivated normal human plasma for constructing the calibration curve will be more accurate in this test method than use of molecular weight markers as described by Furlan (page 4230, Fig. 10, bottom of the legend), and the use of cell extract as test medium is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was

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made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

5. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

A handwritten signature in black ink, appearing to read 'Michael Meller', with a long horizontal line extending to the right.

**MICHAEL MELLER
PRIMARY EXAMINER**

B Shen

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